UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/776,914 | 02/11/2004 | Gerhard Schmid | SCHMID, G. ET AL.-1 | 3052 |

25889 7590 03/18/2008

COLLARD & ROE, P.C.
1077 NORTHERN BOULEVARD
ROSLYN, NY 11576

| EXAMINER | |
|---|---|
| MAEWALL, SNIGDHA | |
| ART UNIT | PAPER NUMBER |
| 1612 | |
| MAIL DATE | DELIVERY MODE |
| 03/18/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/776,914 | SCHMID ET AL. | |
| | Examiner | Art Unit | |
| | Snigdha Maewall | 1612 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 14-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Summary

1. Receipt of Applicant's Arguments/Remarks and RCE filed on 12/20/07 is acknowledged.

Claims 1, 10, 11 and 15 have been amended by the Applicants. Claims 12-13 remain cancelled by the Applicants. Accordingly, claims **1-11 and 14-15** are pending in this application and claims **1-11 and 14-15** will be examined on the merits.

### *Request for Continued Examination*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/17/06 has been entered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 , 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 recite the limitation of "effective amount", however there is no effective amount stated in the claims rendering the claims indefinite. It is unclear what the effective amount is intended to be.

Claim 14 recites the limitation '2-10%. The claim is indefinite as it is not clear whether the Applicant intends to refer to total weight or some other weight. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Artisa et al. (US Pg Pub No. 2005/0019375 A1) in view of Suzuki et al. (JP 6-094912) and further in view of Mayer Davis (Diabetes care volume 24, April 2001), International Diabetes federation (Fact Sheet Impaired Glucose tolerance) and Van Laere et al. (US PG pub 2003/0113310 A1).

Artisa et al. discloses a composition and method that relate to fat containing consumable food products comprising .alpha.-cyclodextrin. The food products have

reduced levels of bioavailable fat but have substantially the same fat, cholesterol and caloric content as a like food without .alpha.-cyclodextrin. The invention also relates to methods for reducing the bioavailability of fats in fat containing food products without reducing caloric intake as determined by bomb calorimetry and to methods for increasing high density lipoproteins in a subject and reducing or controlling weight by administering the food products comprising alpha cyclodextrin (abstract).
Artisa et al. discloses that the total cyclodextrin in the foods is less than about 9-10% w/w, preferably less than about 6%, and more preferably below 3% w/w, and particularly in the case of fat containing consumable farinaceous food products, the amount of total cyclodextrin is below about 3% w/w. The .alpha.-cyclodextrin composition that is used in the products and methods is a substantially pure .alpha.-cyclodextrin comprising at least about 95% .alpha.-cyclodextrin, preferably at least 98% .alpha.-cyclodextrin . Artisa et al. further discloses that the consumable products comprising alpha- cyclodextrin are a dairy food product, a prepared vegetable product, or a prepared meat product, e.g. a prepared beef, lamb, pork, poultry or seafood food product. The consumable food products are suitable for consumption by mammals, e.g., mice, rats, cats, dogs and humans but preferably humans (page 4, [0023]).

The consumable food product is a diet food that inhibits the rate of weight gain, promotes weight loss and provides other health benefits (page 4, paragraph [0024]). Artisa et al. further disclose that by ingesting alpha.-cyclodextrin in an appropriate amount with a fat-containing meal, or shortly before or after ingesting a fat-containing meal, a subject may complex the ingested fat and inhibit its absorption by the body

(page 5, paragraph [0028]).

Artisa et al. does not specifically teach reducing the glycemic index of the food. Suzuki discloses that alpha- cyclodextrin and the composition with alpha –cyclodextrin as the major component have specific biological effects. One of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction and the second effect is suppression of blood triglyceride concentration at a low level by inhibiting liver triglyceride accumulation.(page 6, paragraph 2). Alpha cyclodextrin and its composition helps in treatment of obesity and is important in treatment of hypertriglycemia, arteriosclerosis and triglyceride acuumulative fatty liver (page 6, paragraph2). Suzuki discloses administering alpha-cyclodextrin containing composition to a subject and the alpha-cyclodextrin is present in the Composition in amounts of 10-40% (Examples 1-5 and page 7 of the translation); the alpha-cyclodextrin can be used in the form of powder, granules, aqueous solution (page 7). Suzuki discloses that alpha-cyclodextrin has an inhibitory effect on body weight gain and is administered food at 12-25g/kg body weight for the total cyclodextrin or at 6-13g/kg body weight for the alpha-cyclodextrin (page 4). Therefore it is apparent that alpha-cyclodextrin inherently reduces the glycemic index of the food comprising alpha cyclodextrin.

Mayer-Davis teaches that lifestyle changes can result in improved glucose tolerance among individuals at high risk for developing type 2 diabetes. A reduced-fat diet may result in sustained improvements in glycemic status after 5 years. [first paragraph].

The International Diabetes Federation teaches that weight loss can reduce insulin resistance and make the insulin produced more effective at controlling blood glucose.

Van Laere et al. teaches method for the treatment of obesity, overweight and fluctuations in blood insulin and/or glucose levels (title). Van Laere discloses by referring to US patent 4,396,602 a method of lowering the blood glucose level in mammals. The method comprises administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides. The blood glucose level-lowering agent comprises the enzyme capable of synthesizing sparingly-digestible polysaccharides or oligosaccharides from easily-digestible saccharides, such as monosaccharides, oligosaccharides and polysaccharides. Enzymes providing the above effect are dextransucrase and cyclodextrin-synthesizing enzymes. (see paragraph[0005] on page 1). It is therefore apparent that cyclodextrin helps in lowering of blood glucose since the cyclodextrin synthesizing hormones help in lowering the blood glucose level.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify food having a glycemic index by reducing the glycemic index of the food comprising alpha-cyclodextrin and administering the same to an individual or individuals with impaired glucose tolerance because Artisa et al. teaches reduction of fat by using alpha-cyclodextrin, Suzuki teaches weight gain inhibitory effects due to alpha-cyclodextrin and its relationship in reducing glucose concentration, Mayer teaches that reduced fat diet may result in improvements in glycemic status and

International Federation teaches controlling blood glucose with low fat diet and Van Laere teaches a method of administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides by the help of cyclodextrin synthesizing hormones (which indirectly proves that cyclodextrin helps in synthesizing sparingly-digestible saccharides from easily-digestible saccharides).
A skilled artisan would have been motivated to do so with an expectation of success because it is known in the art that alpha-cyclodextrin helps in reducing fat which in turn helps in improvements in glycemic improvements. With regards to various concentration, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan at the time the invention was made absent evidence to the contrary. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

6. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(b) as being unpatentable over Suzuki et al. (JP 6-094912) in view of Mayer Davis (Diabetes care volume 24, April 2001) and International Diabetes federation (Fact Sheet Impaired Glucose tolerance) and Van Laere et al. (US PG pub 2003/0113310 A1).

The teachings of Mayer Davis (Diabetes care volume 24, April 2001) and International Diabetes federation (Fact Sheet Impaired Glucose tolerance) have been discussed above.

Suzuki discloses that alpha- cyclodextrin and the composition with alpha –cyclodextrin as the major component have specific biological effects. One of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction and the second effect is suppression of blood triglyceride concentration at a low level by inhibiting liver triglyceride accumulation.(page 6, paragraph 2). Alpha cyclodextrin and its composition helps in treatment of obesity and is important in treatment of hypertriglycemia, arteriosclerosis and triglyceride acuumulative fatty liver (page 6, paragraph2). Suzuki discloses administering alpha-cyclodextrin containing composition to a subject and the alpha-cyclodextrin is present in the composition in amounts of 10-40% (Examples 1-5 and page 7 of the translation); the alpha-cyclodextrin can be used in the form of powder, granules, aqueous solution (page 7). Suzuki discloses that alpha-cyclodextrin has an inhibitory effect on body weight gain and is administered food at 12-25g/kg body weight for the total cyclodextrin or at 6-13g/kg body weight for the alpha-cyclodextrin (page 4). Therefore it is apparent that alpha-cyclodextrin inherently reduces the glycemic index of the food comprising alpha cyclodextrin.

Van Laere et al. teaches method for the treatment of obesity, overweight and fluctuations in blood insulin and/or glucose levels (title). Van Laere discloses by referring to US patent 4,396,602 a method of lowering the blood glucose level in

mammals. The method comprises administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides. The blood glucose level-lowering agent comprises the enzyme capable of synthesizing sparingly-digestible polysaccharides or oligosaccharides from easily-digestible saccharides, such as monosaccharides, oligosaccharides and polysaccharides. Enzymes providing the above effect are dextransucrase and cyclodextrin-synthesizing enzymes. (see paragraph[0005] on page 1). It is therefore apparent that cyclodextrin helps in lowering of blood glucose since the cyclodextrin synthesizing hormones help in lowering the blood glucose level.

It would have been obvious to one of ordinary skilled in the art at the time the invention was made to modify food having a glycemic index by reducing the glycemic index of the food comprising alpha-cyclodextrin and administering the same to an individual or individuals with impaired glucose tolerance because Suzuki teaches weight gain inhibitory effects due to alpha-cyclodextrin and its relationship in reducing glucose concentration, Mayer teaches that reduced fat diet may result in improvements in glycemic status, International Federation teaches controlling blood glucose with low fat diet and Van Laere teaches a method of administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides by the help of cyclodextrin synthesizing hormones (which indirectly proves that cyclodextrin helps in synthesizing sparingly-digestible saccharides from easily-digestible saccharides).A skilled artisan would have been motivated to do so with an expectation of success because it is known in the art that alpha-cyclodextrin helps in reducing fat

which in turn helps in improvements in glycemic improvements. With regards to various concentration, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan at the time the invention was made absent evidence to the contrary. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

7. Claims 1-11 and 14-15 are rejected under 35 U.S.C. 103(b) as being unpatentable over Artisa et al. (US Pg Pub No. 2005/0019375 A1) and further in view of Van Laere et al. (US PG pub 2003/0113310 A1), Augustine et al. (Europeon Journal of Clinical Nutrition (2002) 56, 1049-1071) and JP 4011865.

The teachings of Artisa et al. have been discussed above. Although Artisa et al. teaches that a subject may complex the ingested fat with alpha-cyclodextrin and inhibit its absorption by the body (page 5, paragraph [0028]). Artisa et al. do not specifically teach reduction of glycemic index of food comprising alpha-cyclodextrin.

Van Laere et al. teaches method for the treatment of obesity, overweight and fluctuations in blood insulin and/or glucose levels (title). Van Laere discloses by referring to US patent 4,396,602 a method of lowering the blood glucose level in mammals. The method comprises administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides. The blood glucose

level-lowering agent comprises the enzyme capable of synthesizing sparingly-digestible polysaccharides or oligosaccharides from easily-digestible saccharides, such as monosaccharides, oligosaccharides and polysaccharides. Enzymes providing the above effect are dextransucrase and cyclodextrin-synthesizing enzymes. (see paragraph[0005] on page 1). It is therefore apparent that cyclodextrin helps in lowering of blood glucose since the cyclodextrin synthesizing hormones help in lowering the blood glucose level.

Augustine et al. discloses that the glycemic index ranks foods based on their postprandial blood glucose response. Hyperinsulinemia and insulin resistance as well as determinants (e.g. high energy intake, obesity and lack of physical activity have been implicated in the etiology of diabetes. Low glycemic index foods characterized by slowly absorbed carbohydrates have been shown to produce beneficial effect on glucose control, hyperinsulinemia, blood lipids satiety.

JP teaches liquid food additive inhibit glucose absorption treat diabetes obesity comprising extract gymnema leaf cyclodextrin (title). The extract shows sweet taste inhibiting activity and sugar absorption inhibiting activity (see abstract).
Based on the teachings of the above references it would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate alpha-cyclodextrin in the food because the method of administering an enzyme capable of synthesizing sparingly-digestible saccharides from easily-digestible saccharides by the help of cyclodextrin synthesizing hormones (which indirectly proves that cyclodextrin helps in synthesizing sparingly-digestible saccharides from easily-digestible

saccharides). One skilled in the art would have been motivated to incorporate alpha-cyclodextrin because Augustine on the similar end teaches that low glycemic index foods characterized by slowly absorbed carbohydrates have been shown to produce beneficial effect on glucose control, hyperinsulinemia, blood lipids satiety. Further motibvated by the JP's teachings, that Gymnema cyclodextrin leaf extract shows sugar absorption inhibiting activity, one skilled in the art would have modified food by reducing the glycemic index by combining the food with alpha-cyclodextrin with a reasonable expectation of success. One would have been further motivated to prepare a food product comprising alpha-cyclodextrin for the consumption of humans suffering from diabetes because JP reference teaches that alphacyclodextrin helps in inhibiting glucose absorption. One skilled would have been motivated to prepare food comprising alpha-cyclodextrin for pets because Artisa et al. discloses that the consumable food products are suitable for consumption by mammals, e.g., mice, rats, cats, dogs and humans but preferably humans (page 4, [0023]). The invention as a whole would thus have been obvious in view of the cited references to one of ordinary skilled in the art at the time the invention was made. With regards to various concentration, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan at the time the invention was made absent evidence to the contrary. Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

***Response to Arguments***

8. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612

/Snigdha Maewall/
Examiner, Art Unit 1612